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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,450

01/07/2005

Giorgio Cavillini

2818-217

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01/25/2008

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EXAMINER

KUDLA, JOSEPH S

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

01/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/510,450

**Applicant(s)**

CAVILLINI ET AL.

**Examiner**

Joseph S. Kudla

**Art Unit**

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 9, 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/7/2004.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Specification***

1. This application is the U.S. National Phase of International Application PCT/1T03/00214, filed on April 8, 2003 and claims priority to Italian Application No. RM2002A000194, filed April 9, 2002. Priority is acknowledged.

A Preliminary Amendment Filed October 7, 2004, in which priority information is updated, is acknowledged. Claims 1-15 are presented and represent all of the claims under consideration. Claims 1-15 are interpreted as being drawn to **methods of preparation**.

A new Abstract is noted.

***Information Disclosure Statement***

2. The Information Disclosure Sheet (IDS) correspondence submitted by Applicant on October 7, 2004 is acknowledged.

***Abstract***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The

abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because the length of the narrative describing the invention is too short in length to accurately convey Applicant's invention. Correction is required. See MPEP § 608.01(b).

### ***Specification***

#### ***Arrangement of the Specification***

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### ***Content of Specification***

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
  - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of

the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

- (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each

element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

4. The specification of a utility application should include the above sections in order. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading. Specifically, none of the section headings or a disclosure of joint research agreements are present.

Appropriate action is required.

### ***Claim Objections***

5. Claims 9 and 12 are objected to because of the following informalities: Instant claim 9 contains an extra "and" on page 5, line 2 of the instant claims. The presence of the conjunction leads one reading the claim to believe there are two anion species attached to the carnitine. The Examiner believes this extra word was included in error and will read the claim as such. Instant claim 12 contains the letters "cui" in the first

sentence of instant claim 12. The Examiner believes Applicant intended the word to be "which," because of the similarity to instant claim 13 and will read the claim as such. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide adequate written description for the preparation of a medicament for the treatment of oligoasthenoteratospermia. The instant disclosure does not teach by example, or prior art incorporated by reference, a process for the manufacture of the pharmaceutical composition of the three forms of carnitine. Without this disclosure, applicant lacks adequate written description.



7. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims without undue experimentation to manufacture a pharmaceutical composition of L-carnitine, acetyl L-carnitine and propionyl L-carnitine.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;

- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

### **The breadth of the claims**

The breadth of the instant claims is extremely broad in scope for the types of processing steps that could be performed in the manufacture of a pharmaceutical composition of L-carnitine, acetyl L-carnitine and propionyl L-carnitine. Applicant has not provided sufficient evidence to support a claim set drawn to a process of manufacturing outlined in the instant claim set. The breadth of the claims exacerbates the complex nature of the subject matter to which the present claims are directed.

### **The nature of the invention**

The instant claim set outlines a process of manufacture of L-carnitine, acetyl L-carnitine and propionyl L-carnitine. Unit dosages and molar ratios of L-carnitine, acetyl L-carnitine and propionyl L-carnitine are disclosed. The composition can be administered as a nutritional supplement or a medicament for the treatment of oligoasthenoteratospermia.

### **The state of the prior art**

Prior art in the field shows it is well known to those of ordinary skill in the art that

pharmaceutical formulation has always been more of an art than a science. The physical properties that are theoretically expected when combining excipients and active substances are not the "real world" results one usually obtains. Obtaining the best formulation is often done through a series of adjustments to arrive at a final formulation. This can be adequately exemplified in an application for the preparation of analgesic compositions (Iversen, WIPO Application number WO 99/18967, page 8, lines 6 to page 11 line 31).

**The amount of direction provided by the inventor and the existence of working examples**

The instant specification does not provide adequate guidance, which would allow the skilled artisan to extrapolate from the disclosure provided, to practice the claimed methods commensurate in the scope with the instant claims. Applicant provides no guidance or examples on the process of manufacture of the pharmaceutical composition. Adequate enablement requires more than a mere statement of a process for the manufacture of a pharmaceutical composition. Adequate guidance that would serve to enable the invention would be disclosure of specific processing steps (e.g., granulation, sieving, blending) with defined amounts of material and then demonstration that the process controls were adequate and reflected a manufacturing process that was repeatable (e.g., content uniformity, particle size, composite assay, etc.). Applicant has no disclosure of these parameters.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation (*In re Wright*, 999 F. 2d 1557, 1562; 27 USPQ 2d 1510, 1514 (Fed. Cir. 1993)). The specification lacks sufficient disclosure to support applicant's claims of a process of manufacture for a pharmaceutical composition of L-carnitine, acetyl L-carnitine and propionyl L-carnitine. There is not seen sufficient working examples or data from references in the prior art providing a nexus between that which applicant asserts to support a process of manufacture and the amount of disclosure Applicant has actually provided.

**The quantity of experimentation needed to make and use the invention based on the content of the disclosure**

Based on the unpredictable nature of the invention, the state of the prior art and the breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation. The essential elements towards the validation of a manufacturing process require close attention to process controls and analytical testing to confirm results. Again to repeat what was stated above, pharmaceutical formulation has always been more of an art than a science. The physical properties that are theoretically expected when combining excipients and active substances are not the "real world" results one usually obtains. Obtaining the best formulation is often done through a series of adjustments to arrive at a final formulation.

Based on the unpredictable nature of the invention, the state of the prior art and the extreme breadth of the claims, one skilled in the art could not practice the claimed invention without undue experimentation.

8. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

Claims 1-15 provide for the use of L-carnitine, acetyl L-carnitine and propionyl L-carnitine, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 14 recites the limitation "the nutritional composition" in lines 2 and 3 of the instant claim. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 101***

9. Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Fassi et al. (US Patent 6,255,346).

Fassi et al. teach the preparation of a composition of L-carnitine, acetyl L-carnitine and propionyl L-carnitine or their pharmacologically acceptable salts for use in a nutritional, food, dietary supplement or medicine (Abstract). Fassi et al. also teach the identity of the pharmacologically acceptable salts on page 1, column 2, lines 51-58.

11. Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Fassi (WIPO Application WO03/066573).

Fassi teaches the preparation of mixed salts for use as dietary supplements and pharmaceutical compositions in the treatment of sexual disorders in male subjects (Abstract and Title). Fassi teaches that the sexual disorders include sperm motility (abstract) and sub-fertile subjects (low concentration of spermatozoa) (page 2, paragraph 3, line 3) and altered sperm morphology (teratospermia) (page 3, paragraph 6, line 3). Fassi teaches that a composition for the amelioration of these conditions includes a composition of L-carnitine, acetyl L-carnitine and propionyl L-carnitine and

their pharmacologically acceptable salts (page 9, paragraph 3). Fassi also teaches examples of such pharmacologically acceptable salts in reference claim 19.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Cavazza (WIPO Application WO99/27925 and cited by applicant hereinafter Cavazza925), in view of Cavazza (European Union Application EP 0 539 336, cited by applicant hereinafter Cavazza336).

Cavazza925 teaches a preparation of L-carnitine and acetyl L-carnitine and pharmacologically acceptable salts to treat idiopathic asthenozoospermia and sperm quality (Abstract). Cavazza925 also teaches the administration of said preparation "significantly increased the concentration and motility of spermatozoa" (page 7, paragraph 2, lines 1-2). Cavazza925 teaches examples of pharmacologically acceptable salts on page 7, last two lines to page 8, line 3). Cavazza925 teaches the administration of the preparation can be as a food supplement, a nutritional supplement or as a therapeutic product (page 5, first paragraph). Ratios and unit doses of the preparation are disclosed on page 5, paragraphs 2-5).

Cavazza925 does not teach the use of propionyl L-carnitine in the preparation.

Cavazza336 teaches the use of L-carnitine with propionyl L-carnitine in the preparation of a medicament for the treatment of idiopathic oligoasthenospermia (Abstract and reference claims 1 and 4). Cavazza336 also teaches unit dosages for the composition in reference claim 5.

It would have been obvious to one of ordinary skill in the art that if the preparations taught by Cavazza925 which includes L-carnitine and acetyl L-carnitine and pharmacologically acceptable salts for the treatment of quality, concentration and motility of sperm and Cavazza336 which includes L-carnitine with propionyl L-carnitine in the preparation of a medicament for the treatment of idiopathic oligoasthenospermia, a preparation of all of the elements of both preparations would similarly be useful in treating oligoasthenoteratospermia. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or



workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%). Therefore, no more than routine experimentation would have been necessary to one of ordinary skill in the art to be able to arrive at both the administration unit dosages recited in instant claims 14 and 15 and the molar ratio for producing the formulation, as in instant claims 11 and 12.

Therefore, the teachings of Cavazza925, in view of Cavazza336, render the claimed invention obvious.

No claims are allowed.

### ***Conclusion***

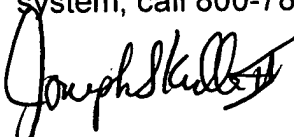
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

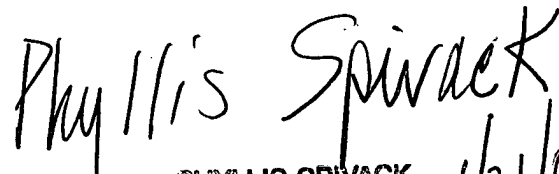
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
JK

  
PHYLLIS SPIVACK  
PRIMARY EXAMINER 1/21/08